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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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IN RE:	:
Fosamax Products Liability Litigation	: 1:06-md-1789 (JFK)
	:
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<i>This Document Relates to:</i>	: ANSWER AND AFFIRMATIVE
Michele Bard	: DEFENSES OF MERCK
v. Merck & Co., Inc., et al.	: & CO., INC.;
	: DEMAND FOR JURY TRIAL
Case No: 1:07-cv-7212-JFK	:
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Defendant, Merck Co., Inc. ("Merck"), by and through its undersigned attorneys, hereby answers the Complaint. Merck denies all allegations set forth in the Complaint directed to Merck, except to the extent such allegations are specifically admitted below:

I. JURISDICTION AND VENUE

1. The allegations of the first sentence of Paragraph 1 are conclusions of law to which no response is required. To the extent that a response is required, Merck denies each and every allegation of the first sentence of Paragraph 1. As to the allegations of the second sentence of Paragraph 1, Merck is without knowledge or information sufficient to form a belief as to these allegations. Merck admits the allegations of the third sentence of Paragraph 1. The allegations of the fourth sentence of Paragraph 1 are not directed to

Merck and therefore no response is required. To the extent a response is required, Merck states that it is without knowledge or information sufficient to form a belief as to the allegations of the fourth sentence of Paragraph 1. Merck is without knowledge as to the allegations in the fifth sentence of Paragraph 1, but for jurisdictional purposes only, admits that Plaintiff seeks in excess of \$75,000.

2. The allegations of Paragraph 2 are conclusions of law to which no response is required. To the extent a response is required, Merck denies the allegations of Paragraph 2, except admits that Merck is authorized to do business in, among other states, Florida, and states that it is without knowledge as to the allegations directed to Novartis.

II. PARTIES

3. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 3.

4. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 4.

Defendant Merck

5. Merck admits that it is a corporation organized under the laws of the State of New Jersey with its principal place of business in New Jersey. Except as expressly admitted herein, Merck denies the remaining allegations of Paragraph 5.

6. Merck admits that it is registered to do business in the State of Florida.

7. Merck is without knowledge as to what is meant by the phrase “regularly transacted,” so the allegations in Paragraph 7 are denied.

8. Merck denies each and every allegation of Paragraph 8, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® in accordance with its approved prescribing information. Merck denies any allegations in Paragraph 8 inconsistent with that prescribing information and respectfully refers the Court to the Physicians' Desk Reference ("PDR") for FOSAMAX® for its actual language and full text.

9. Merck admits only that it distributed FOSAMAX® for prescription in accordance with its approved prescribing information and denies any allegations in Paragraph 9 inconsistent with that prescribing information. Merck respectfully refers the Court to the PDR for FOSAMAX® for its actual language and full text. Except as expressly admitted herein, Merck denies the remaining allegations of Paragraph 9.

10. Merck is without knowledge as to what is meant by the phrase "substantial revenue," so the allegations in Paragraph 10 are denied.

11. Merck is without knowledge as to what is meant by "consequences," so the allegations in Paragraph 11 are denied.

Defendant Novartis

12. The allegations of Paragraph 12 are not directed to Merck and therefore no response is required. To the extent a response is required, Merck states that it is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 12.

13. The allegations of Paragraph 13 are not directed to Merck and therefore no response is required. To the extent a response is required, Merck states that it is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 13.

14. The allegations of Paragraph 14 are not directed to Merck and therefore no response is required. To the extent a response is required, Merck states that it is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 14.

15. The allegations of Paragraph 15 are not directed to Merck and therefore no response is required. To the extent a response is required, Merck states that it is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 15.

16. The allegations of Paragraph 16 are not directed to Merck and therefore no response is required. To the extent a response is required, Merck states that it is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 16.

17. The allegations of Paragraph 17 are not directed to Merck and therefore no response is required. To the extent a response is required, Merck states that it is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 17.

III. SUMMARY OF THE CASE

18. Merck denies each and every allegation of Paragraph 18, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

19. The allegations of Paragraph 19 are not directed to Merck and therefore no response is required. To the extent a response is required, Merck states that it is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 19.

20. To the extent the allegations of Paragraph 20 are directed to Merck, Merck denies each and every allegation of Paragraph 20. To the extent the allegations of Paragraph 20 are not directed to Merck, no response is required. To the extent a response

is required, Merck states that it is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 20

21. Merck denies each and every allegation of Paragraph 21.

22. The allegations of Paragraph 22 are not directed to Merck and therefore no response is required. To the extent a response is required, Merck states that it is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 22.

23. To the extent the allegations of Paragraph 23 are directed to Merck, Merck denies each and every allegation of Paragraph 23. To the extent the allegations of Paragraph 23 are not directed to Merck, no response is required. To the extent a response is required, Merck states that it is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 23.

24. Merck denies each and every allegation of Paragraph 24.

IV. FACTUAL BACKGROUND

25. Merck denies each and every allegation of Paragraph 25, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

26. Merck denies each and every allegation of Paragraph 26, except that Merck admits that it sought and, in 1995, first obtained FDA approval to manufacture and market FOSAMAX® 10 mg and FOSAMAX® 40 mg tablets, a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information. Merck denies any allegations in Paragraph 26 inconsistent with that prescribing information.

27. The allegations of Paragraph 27 are not directed to Merck and therefore no response is required. To the extent a response is required, Merck states that it is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 27.

28. The allegations of Paragraph 28 are not directed to Merck and therefore no response is required. To the extent a response is required, Merck states that it is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 28.

29. Merck admits only that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information and denies any allegations in Paragraph 29 inconsistent with that prescribing information. Merck also refers the Court to the prescribing information for Actonel, Aredia, and Zometa, and denies any allegations in Paragraph 29 with respect to Actonel, Aredia, and Zometa inconsistent with that prescribing information.

30. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 30.

31. Merck admits only that some bisphosphonates contain nitrogen and some do not and that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information. Merck denies any allegations in Paragraph 31 inconsistent with that prescribing information. Merck respectfully refers the Court to the PDR for FOSAMAX® for its actual language and full text. Merck also refers the Court to the prescribing information for Aredia, Boniva, Actonel, Didronel, Bonefos, Loron, and Skelid, and denies any allegations in Paragraph 31 with respect to Aredia, Boniva, Actonel, Didronel, Bonefos, Loron, and Skelid

inconsistent with that prescribing information. Merck denies the remaining allegations of Paragraph 31.

32. Merck denies each and every allegation of Paragraph 32.

33. Merck denies each and every allegation of Paragraph 33.

34. To the extent the allegations of Paragraph 34 are directed to Merck, Merck denies each and every allegation of Paragraph 34. To the extent the allegations of Paragraph 34 are not directed to Merck, no response is required. To the extent a response is required, Merck states that it is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 34.

35. To the extent the allegations of Paragraph 35 are directed to Merck, Merck denies each and every allegation of Paragraph 35. To the extent the allegations of Paragraph 35 are not directed to Merck, no response is required. To the extent a response is required, Merck states that it is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 35.

36. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 36.

37. Merck denies each and every allegation of Paragraph 37.

38. Merck denies each and every allegation of Paragraph 38.

39. Merck denies each and every allegation of Paragraph 39.

40. Merck denies each and every allegation of Paragraph 40.

41. Merck denies each and every allegation of Paragraph 41, except that Merck admits that the FDA drafted an "ODS Postmarketing Safety Review," but respectfully refers the Court to said document for its actual language and full text.

42. Merck denies each and every allegation of Paragraph 42.

43. Merck denies each and every allegation of Paragraph 43.

44. The allegations of Paragraph 44 are not directed to Merck and therefore no response is required. To the extent a response is required, Merck states that it is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 44.

45. To the extent the allegations of Paragraph 45 are directed to Merck, Merck denies each and every allegation of Paragraph 45. To the extent the allegations of Paragraph 45 are not directed to Merck, no response is required. To the extent a response is required, Merck states that it is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 45.

46. To the extent the allegations of Paragraph 46 are directed to Merck, Merck denies each and every allegation of Paragraph 46. To the extent the allegations of Paragraph 46 are not directed to Merck, no response is required. To the extent a response is required, Merck states that it is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 46.

47. Merck denies each and every allegation of Paragraph 47.

48. Merck denies each and every allegation of Paragraph 48.

49. Merck denies each and every allegation of Paragraph 49.

50. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 50.

51. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 51.

52. Merck denies each and every allegation of Paragraph 52.

53. Merck denies each and every allegation of Paragraph 53.

54. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 54.

55. Merck denies each and every allegation of Paragraph 55.

56. Merck denies each and every allegation of Paragraph 56.

57. Merck denies each and every allegation of Paragraph 57.

COUNTS

COUNT I: NEGLIGENCE

58. Merck repleads its answers to Paragraphs 1 through and including 57, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

59. The allegations in Paragraph 59 are conclusions of law to which no response is required; to the extent that a response is deemed necessary, the allegations are denied and Merck respectfully refers the Court to the relevant legal standard, including any conflict of law rules.

60. To the extent the allegations of Paragraph 60 are directed to Merck, Merck denies each and every allegation of Paragraph 60, including each and every allegation contained in subparts (a) through (f). To the extent the allegations of Paragraph 60 are not directed to Merck, no response is required. To the extent a response is required, Merck states that it is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 60.

61. Merck denies each and every allegation of Paragraph 61.

62. Merck denies each and every allegation of Paragraph 62.

COUNT II: STRICT LIABILITY

63. Merck repleads its answers to Paragraphs 1 through and including 62, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

64. To the extent the allegations of Paragraph 64 are directed to Merck, Merck denies each and every allegation of Paragraph 64, except that it admits that Merck manufactured, marketed and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information. To the extent the allegations of Paragraph 64 are not directed to Merck, no response is required. To the extent a response is required, Merck states that it is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 64.

65. To the extent the allegations of Paragraph 65 are directed to Merck, Merck denies each and every allegation of Paragraph 65, except that it admits that Merck manufactured, marketed and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information and states that it is without knowledge as to the condition of the FOSAMAX® Plaintiff alleges he consumed. To the extent the allegations of Paragraph 65 are not directed to Merck, no response is required. To the extent a response is required, Merck states that it is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 65.

66. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 66.

67. To the extent the allegations of Paragraph 67 are directed to Merck, Merck denies each and every allegation of Paragraph 67. To the extent the allegations of

Paragraph 67 are not directed to Merck, no response is required. To the extent a response is required, Merck states that it is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 67.

68. To the extent the allegations of Paragraph 68 are directed to Merck, Merck denies each and every allegation of Paragraph 68. To the extent the allegations of Paragraph 68 are not directed to Merck, no response is required. To the extent a response is required, Merck states that it is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 68.

69. To the extent the allegations of Paragraph 69 are directed to Merck, Merck denies each and every allegation of Paragraph 69. To the extent the allegations of Paragraph 69 are not directed to Merck, no response is required. To the extent a response is required, Merck states that it is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 69.

70. To the extent the allegations of Paragraph 70 are directed to Merck, Merck denies each and every allegation of Paragraph 70. To the extent the allegations of Paragraph 70 are not directed to Merck, no response is required. To the extent a response is required, Merck states that it is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 70.

71. To the extent the allegations of Paragraph 71 are directed to Merck, Merck denies each and every allegation of Paragraph 71. To the extent the allegations of Paragraph 71 are not directed to Merck, no response is required. To the extent a response is required, Merck states that it is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 71.

72. To the extent the allegations of Paragraph 72 are directed to Merck, Merck denies each and every allegation of Paragraph 72. To the extent the allegations of Paragraph 72 are not directed to Merck, no response is required. To the extent a response is required, Merck states that it is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 72.

73. Merck denies each and every allegation of Paragraph 73.

74. Merck denies each and every allegation of Paragraph 74.

COUNT III: BREACH OF EXPRESS WARRANTY

75. Merck repleads its answers to Paragraphs 1 through and including 74, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

76. Merck denies each and every allegation of Paragraph 76, and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained therein. Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information.

77. The allegations of Paragraph 77 are not directed to Merck and therefore no response is required. To the extent a response is required, Merck states that it is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 77.

78. To the extent the allegations of Paragraph 78 are directed to Merck, Merck denies each and every allegation of Paragraph 78. To the extent the allegations of Paragraph 78 are not directed to Merck, no response is required. To the extent a response

is required, Merck states that it is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 78.

79. To the extent the allegations of Paragraph 79 are directed to Merck, Merck denies each and every allegation of Paragraph 79. To the extent the allegations of Paragraph 79 are not directed to Merck, no response is required. To the extent a response is required, Merck states that it is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 79.

80. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 80.

81. Merck denies each and every allegation of Paragraph 81.

82. Merck denies each and every allegation of Paragraph 82.

COUNT IV: BREACH OF IMPLIED WARRANTY

83. Merck repleads its answers to Paragraphs 1 through and including 82, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

84. Merck denies each and every allegation of Paragraph 84, except that Merck admits that it manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

85. The allegations of Paragraph 85 are not directed to Merck and therefore no response is required. To the extent a response is required, Merck states that it is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 85.

86. To the extent the allegations of Paragraph 86 are directed to Merck, Merck denies each and every allegation of Paragraph 86, and respectfully refers the Court to the

FDA-approved prescribing information for any and all representations contained therein. Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information. To the extent the allegations of Paragraph 86 are not directed to Merck, no response is required. To the extent a response is required, Merck states that it is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 86.

87. To the extent the allegations of Paragraph 87 are directed to Merck, Merck denies each and every allegation of Paragraph 87. To the extent the allegations of Paragraph 87 are not directed to Merck, no response is required. To the extent a response is required, Merck states that it is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 87.

88. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 88.

89. To the extent the allegations of Paragraph 89 are directed to Merck, Merck denies each and every allegation of Paragraph 89. To the extent the allegations of Paragraph 89 are not directed to Merck, no response is required. To the extent a response is required, Merck states that it is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 89.

90. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 90.

91. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 91.

92. Merck denies each and every allegation of Paragraph 92.

93. Merck denies each and every allegation of Paragraph 93.

COUNT V: FRAUDULENT MISREPRESENTATION

94. Merck repleads its answers to Paragraphs 1 through and including 93, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

95. Merck denies each and every allegation of Paragraph 95, including each and every allegation contained in subparts (a) through (c).

96. Merck denies each and every allegation of Paragraph 96.

97. Merck denies each and every allegation of Paragraph 97.

98. Merck denies each and every allegation of Paragraph 98.

99. Merck denies each and every allegation of Paragraph 99.

100. Merck denies each and every allegation of Paragraph 100.

101. Merck denies each and every allegation of Paragraph 101.

102. Merck denies each and every allegation of Paragraph 102.

COUNT VI: FRAUDULENT CONCEALMENT

103. Merck repleads its answers to Paragraphs 1 through and including 102, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

104. Merck denies each and every allegation of Paragraph 104, including each and every allegation contained in subparts (a) through (b).

105. Merck denies each and every allegation of Paragraph 105.

106. Merck denies each and every allegation of Paragraph 106.

107. Merck denies each and every allegation of Paragraph 107.

108. Merck denies each and every allegation of Paragraph 108.

109. Merck denies each and every allegation of Paragraph 109

110. Merck denies each and every allegation of Paragraph 110.

COUNT VII: JOINT AND SEVERAL LIABILITY

111. Merck repleads its answers to Paragraphs 1 through and including 110, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

112. Merck denies each and every allegation of Paragraph 112.

GLOBAL PRAYER FOR RELIEF

Merck denies that Plaintiff is entitled to any of the relief requested in her Global Prayer for Relief.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiff's Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

AFFIRMATIVE DEFENSES

Discovery and investigation may reveal that any one or more of the following affirmative defenses should be available to Merck in this matter. Merck, therefore, asserts said affirmative defenses in order to preserve the right to assert them. Upon completion of discovery, and if the facts warrant, Merck may withdraw any of these affirmative defenses as may be appropriate. Further, Merck reserves the right to amend its Answer to assert additional defenses, cross-claims, counterclaims, and other claims and defenses as discovery proceeds. Further answering and by way of additional defense, Merck states as follows:

FIRST AFFIRMATIVE DEFENSE

Each and every claim asserted or raised in the Complaint is barred by the applicable statute of limitations and is otherwise untimely.

SECOND AFFIRMATIVE DEFENSE

The Complaint fails to state a claim upon which relief can be granted.

THIRD AFFIRMATIVE DEFENSE

Each and every claim asserted or raised in the Complaint is barred by the doctrines of estoppel, waiver or statutory and regulatory compliance.

FOURTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries or losses were caused in whole or in part through the operation of nature or other intervening cause or causes.

FIFTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff asserts claims based on Merck's adherence to and compliance with applicable state laws, regulations and rules, such claims are preempted by federal law under the Supremacy Clause of the United States Constitution.

SIXTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff asserts claims based upon an alleged failure by Merck to warn Plaintiff directly of alleged dangers associated with the use of FOSAMAX®, such claims are barred under the learned intermediary doctrine because Merck has discharged its duty to warn in its warnings to the prescribing physician.

SEVENTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses were caused in whole or in part by the contributory negligence of the allegedly injured Plaintiff.

EIGHTH AFFIRMATIVE DEFENSE

Any liability that might otherwise be imposed upon this Defendant is subject to reduction by the application of the doctrine of comparative fault and/or negligence.

NINTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses were only sustained after Plaintiff knowingly, voluntarily, and willfully assumed the risk of any injury as the result of the consumption of, administration of, or exposure to any medicine or pharmaceutical preparation manufactured or distributed by Merck or other manufacturer.

TENTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Merck and over whom Merck had no control and for whom Merck may not be held accountable.

ELEVENTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by Plaintiff's misuse or abuse of FOSAMAX®.

TWELFTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses resulted from Plaintiff's pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases, or illnesses, idiosyncratic reactions, subsequent medical conditions or natural courses of conditions for which this Defendant is not responsible.

THIRTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff relies upon any theory of breach of warranty, such claims are also barred for lack of timely notice of breach and/or lack of privity.

FOURTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part under the applicable state law because FOSAMAX® was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

FIFTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part because the product at issue was made in accordance with the state of the art at the time it was manufactured.

SIXTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff seeks punitive damages for the conduct which allegedly caused the injuries asserted in the Complaint, such an award would, if granted, violate Merck's state and federal constitutional rights.

SEVENTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff seeks punitive damages for an alleged act or omission of Merck, no act or omission was malicious, willful, wanton, reckless or grossly negligent and, therefore, any award of punitive damages is barred.

EIGHTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff seeks punitive damages, such claim is barred because FOSAMAX® and its labeling was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

NINETEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part under comment k to Section 402A of the Restatement (Second) of Torts.

TWENTIETH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part because Merck provided legally adequate "directions or warnings" as to the use of FOSAMAX® and any other medicine or pharmaceutical preparation Plaintiff alleges to have taken within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

TWENTY-FIRST AFFIRMATIVE DEFENSE

Plaintiff's claims are barred under Section 4, *et seq.*, of the Restatement (Third) of Torts: Products Liability.

TWENTY-SECOND AFFIRMATIVE DEFENSE

Plaintiff's claims are barred under comment f to Section 6 of the Restatement (Third) of Torts: Products Liability.

TWENTY-THIRD AFFIRMATIVE DEFENSE

There is no practical or technically feasible alternative design that would have reduced the alleged risk without substantially impairing the reasonably anticipated and intended function of FOSAMAX®.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part by failure to mitigate damages.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part because Merck's conduct conforms with medical knowledge.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

With respect to each and every cause of action, Plaintiff is not entitled to recovery for strict liability because Plaintiff cannot state claims founded in strict liability because, among other things, comments j and k to Section 402A of the Restatement (Second) of Torts relegates Plaintiff's claims to a negligence cause of action.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

All activities of Merck as alleged in the Complaint were expressly authorized and/or regulated by a government agency. Therefore, Plaintiff's claims pertaining to unfair or deceptive practices are barred.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

With respect to each and every cause of action, Plaintiff is not entitled to recover because if the product involved was unsafe, which Merck denies, then it was unavoidably unsafe as defined in Restatement of Torts. The apparent benefits of the product exceeded

any apparent risk given the scientific knowledge available when the product was marketed.

TWENTY-NINTH AFFIRMATIVE DEFENSE

Merck's advertisements and labeling with respect to the products which are the subject matter of this action were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States, Florida, and New York Constitutions.

THIRTIETH AFFIRMATIVE DEFENSE

The public interest in the benefit and availability of the product which is the subject matter of this action precludes liability for risks, if any, resulting from any activities undertaken by Defendant, which were unavoidable given the state of human knowledge at the time those activities were undertaken. With respect to Plaintiff's claims, if it is determined there is a risk inherent in the product which is the subject matter of this action, then such risk, if any, is outweighed by the benefit of the product.

THIRTY-FIRST AFFIRMATIVE DEFENSE

At all times relevant herein, any product which is the subject matter of this action manufactured and distributed by Merck in any state in the United States was manufactured and distributed in a reasonable and prudent manner based upon available medical and scientific knowledge and further was processed and distributed in accordance with and pursuant to all applicable regulations of the FDA.

THIRTY-SECOND AFFIRMATIVE DEFENSE

With respect to each and every purported cause of action, the acts of Merck were at all times done in good faith and without malice.

THIRTY-THIRD AFFIRMATIVE DEFENSE

To the extent there were any risks associated with the use of the product which is the subject matter of this action which Merck knew or should have known and which gave rise to a duty to warn, Merck at all times discharged such duty through appropriate and adequate warnings in accordance with federal and state law.

THIRTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiff has not sustained an ascertainable loss of property or money.

THIRTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiff has not suffered any actual injury or damages.

THIRTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiff's claimed are barred under the doctrine of economic loss.

THIRTY-SEVENTH AFFIRMATIVE DEFENSE

This case is more appropriately brought in a different venue as defined in 28 U.S.C. §1404(a).

THIRTY-EIGHTH AFFIRMATIVE DEFENSE

This case is subject to dismissal and/or transfer to another venue pursuant to 28 U.S.C. §1406(a).

THIRTY-NINTH AFFIRMATIVE DEFENSE

This case is subject to dismissal or stay on the grounds of *forum non conveniens*.

FORTIETH AFFIRMATIVE DEFENSE

Plaintiff's claims of fraud are not pleaded with the required particularity.

FORTY-FIRST AFFIRMATIVE DEFENSE

Plaintiff cannot recover for the claims asserted because Plaintiff has failed to comply with the conditions precedent necessary to bring this action and/or each particular cause of action asserted by Plaintiff.

FORTY-SECOND AFFIRMATIVE DEFENSE

Plaintiff's claims for breach of warranty are barred because Plaintiff did not rely on such warranties and the claims are otherwise barred for lack of timely notice, lack of privity and/or because the alleged warranties were disclaimed.

FORTY-THIRD AFFIRMATIVE DEFENSE

An asymptomatic plaintiff lacks standing because she has suffered no damages and no injury-in-fact.

FORTY-FOURTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff asserts claims based on Merck's adherence to and compliance with applicable state laws, regulations and rules, such claims are preempted by federal law under the Final Rule, Requirements on Content and Format of Labeling for Human Prescription Drug and Biologic Products, FDA Docket No. 2000N-1269 (January 24, 2006).

FORTY-FIFTH AFFIRMATIVE DEFENSE

The substantive law of Florida applies to Plaintiff's claims.

Inasmuch as the Complaint does not describe the alleged underlying claims with sufficient particularity to enable Merck to determine all of its legal, contractual and equitable rights, Merck reserves the right to amend and/or supplement the averments of

its Answer to assert any and all pertinent liability defenses ascertained through further investigation and discovery.

Merck will rely on all defenses that may become available during discovery or trial.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiff's Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

JURY DEMAND

Merck demands a trial by jury as to all issues so triable.

DATED: New York, New York
August 29, 2007

Respectfully submitted,

HUGHES HUBBARD & REED LLP

By: /s/
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